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Organic Materials Review Institute
Attn: Brian Baker, Ph.D.
Box 11558
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Dear Dr. Baker:

Thank you for your response to each of our applications submitted for product approval by OMRI. In this letter I address your questions relative to the EC&S CILK™ Dry Feed Additive. Thank you for the offer to send additional supporting documentation relative to whether enzymes could be used in animal feed and if it could be compatible with organic standards.

First, a brief medical and biological background, and then my personal philosophy regarding enzymes and "organic consistency" are presented in this letter. As defined in Mosby's Medical Dictionary, page 431 (Exhibit I, a copy is enclosed): "ENZYME: a protein produced by living cells that catalyzes chemical reactions in organic matter. Most enzymes are produced in minute quantities and catalyze reactions that take place within the cells. Digestive enzymes, however, are produced in relatively large quantities and act outside the cells in the lumen of the digestive tube."

Quoting from the Encyclopedia and Dictionary of Medicine, page 422, (Exhibit II, a copy is enclosed): "ENZYME: any protein that acts as a catalyst increasing the rate at which a chemical reaction occurs. The human body probably contains about 10,000 different enzymes. At body temperature, very few biochemical reactions proceed at a significant rate without the presence of an enzyme. Like all catalysts, an enzyme does not control the directions of the reaction; it increases the rates of the forward and reverse reactions proportionally." In our chemistry classes we observed chemical reactions take place with the heat from a burner, known as "hot" chemistry. However, reactions within living bodies and cells, human, animal or plants cannot function with "hot" chemistry, thus enzymes allow the reactions to evolve with "cold" chemistry.

Exhibit III, Biology: S.S. Mader, pages 108-110, (a copy is enclosed) states "No reaction can occur in a cell unless its own enzyme is present and active... Enzymes are proteins that speed up ("Cold") chemical reactions by lowering the energy of activation. They do this by forming

an enzyme-substrate complex.” Dr. Mader makes another interesting statement, describing an example of the speed of reactive time involved, page 410: “Condition Affecting Enzyme Reactions; Enzymatic reactions proceed quite rapidly. For example, the breakdown of hydrogen peroxide into water and oxygen can occur 600,000 times a second when the enzyme catalase is present. How quickly an enzyme can work however, is affected by certain conditions.”

Personal philosophy now becomes involved. I concur with OMRI’s concern with the involvement of general enzyme approval in an organic program. There is such a vast number of enzymes – 10,000 different kinds work in a human body. Some extreme examples of enzymatic action result in 600,000 reactions per second! We will never live long enough to understand and apply all we might understand about enzyme functions.

On the other hand, we must be aware of the fact that these functions are real and very important. Enzyme functions are a product of microbial life, “all natural” and “organic” quintessentially exemplified! I have been confronted with this issue for some time, and thus consulted numerous “hands on people.” From my research “in the field,” I have concluded that the following elementary principles must be applied:

- A. No “fancy stuff.” Just keep it simple, direct and proven functional.
- B. Follow the principle of the quote from Exhibit I, the Medical Dictionary: “DIGESTIVE ENZYMES, however, are produced (and can be added to a digestive system to counter those not produced due to stress, etc.) in relatively large quantities and act outside of the cells in the lumen of the digestive tube.
- C. Use only a tailored selection of enzymes that follow this criteria:
 - 1. All enzymes except Hemi-cellulase (in the EC&S formulations) are now – today found in the human body, functional and native to humans.
 - 2. Hemi-cellulase is found in every grocery store, in the produce department’s fresh vegetables and fruits.
 - 3. The enzymes used in EC&S CILK™ are only a few of the thousands of enzymes common for humans, and for animals and plants as well.
 - 4. Many enzymes are available from animal sources, BUT SHOULD NOT BE USED.
 - 5. All enzymes added to EC&S CILK™ must be available from items listed as GRAS (“generally regarded as safe”) by the Association of American Feed Control Officials (AAFCO). Thus, the enzymes may be microbial life, and they must meet the standards of AAFCO and the Food and Drug Administration (FDA). The EC&S application presented to OMRI includes a letter that evidences the compliance of EC&S CILK™ with the AAFCO and FDA standards. The

Digestive Aid Enzymes in EC&S CILK™ are derived microbiologically or from natural plant materials. Genetically engineered organisms or viruses are not used nor are synthetic preservatives.

6. The Digestion Aid Enzymes selected for use by EC&S may be enzymes available from plant origin, and are not fortified with synthetic plant nutrients.
7. All enzymes in EC&S CILK™ must be DIGESTION AID ENZYMES ONLY. These enzymes allow digestion through absorption in the gastrointestinal tract.
8. Enzymes used by EC&S are ubiquitous. They are available through the local grocery store, farmers' markets, (in the fresh vegetables and fruits), and in local health food stores, (in bottles of every size and shape). Sections of bookstores are devoted to the explanation and the merits of these specific, somewhat universal enzymes for human use. University trained animal nutritionists and veterinarians prescribe them everyday. Digestion Aid Enzymes, as Enviro Consultant Service, LLC (ECS) has presented, ARE SAFE. ECS could not logically ignore these enzymes, nor can the organic movement continue to ignore them, for some reaction will fill the vacuum. To establish policy early may well be a key.

ECS's responses to the seven questions posed in the OMRI letter dated August 13, 1999, are based upon the previous discussion and the specific enzymes being reviewed, the Digestion Aid Enzymes.

QUESTION 1: The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems.

RESPONSE: The "substance" being considered, Digestion Aid Enzymes in EC&S CILK™, are very common, safe and powerful enzymes. There is no known potential problem relative to a detrimental chemical interaction with other materials used in organic farming systems. Any negative reaction that might occur could be caused by "other materials." Also, when I assisted with some microbial remediation of hazardous materials in the past, it appeared that any residue from these specific enzymes were beneficial. None of the Digestion Aid Enzymes in EC&S CILK™ Dry Feed Additive is pathogenic.

QUESTION 2: The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

RESPONSE: The "substance," Digestion Aid Enzymes, is specific enzymes formulated specifically for EC&S CILK™ Dry Feed Additive, so as not to be toxic when mixed as directed. Only 2.5 pounds of additive is suggested per ton of feed. There are no negative breakdown products, nor are there any known contaminants. Certainly, there are no known negative effects relative to their persistent use, such as forming a harmful concentration in the environment. On the contrary, it is more likely that the Digestion Aid Enzymes will have a

positive effect on the environment, by way of bio-remediation and restoration. (This is not a claim).

QUESTION 3: *The probability of environmental contamination during manufacture, use, misuse or disposal of such substance.*

RESPONSE: The "substance," Digestion Aid Enzymes, is well known for not being hazardous, thus the probability of environmental contamination is remote. The blending process with the anti-caking carrier is done at a blending plant following OSHA dust control advisory. The additive is blended at the feed mill, which also follows OSHA regulations. The anti-caking materials are non-toxic earth elements and have no hazardous disposal problem when returned back to the earth. Use has proven to be positive, misuse could be expensive due to product waste.

QUESTION 4: *The effect of the substance on human health.*

RESPONSE: Relative to material now presented to OMRI as Exhibits I, II, III, IV, V, VI, and VII, plus the volumes of sales materials for the promotion of an improved environment, improved personal health and improved animal health, it appears the effects of the "substance," Digestion Aid Enzymes, benefit human health. All Digestion Aid Enzymes used in EC&S CILK™ are non-pathogenic. Certainly, there are no indications that a prudent person following label instructions, would experience any negative effects. Please see Exhibit 7: The Complete Book of Enzyme Therapy.

QUESTION 5: *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*

RESPONSE: The effects of the "substance," Digestion Aid Enzymes are very positive. The question, "effects of substance on biological and chemical interactions in the agroecosystem," is a great question because it is so general. To answer the question requires a discussion of "all-out-of-doors," and the time to write a very large book. Instead, I will provide the requested general information by answering within a more narrow scope that is pertinent to the Digestion Aid Enzymes. The Digestion Aid Enzymes are part of a dry feed additive, which includes the anti-caking carriers. Two and one-half pounds of the dry feed additive are added to one ton of dry feed. Reports indicate the majority of animals using the EC&S CILK™ experience positive results. There were no reports of negative results relative to any part of the agroecosystem. In fact, there are reports of possible odor reduction, reduced feed consumption, etc. There are reports that it could have positive results assisting the microbiology of the soil. Dr. Arden B. Anderson, Ph.D., in his book Science in Agriculture, relates research which records investigation of 130 different bacteria, mycobacterium, and actinomycetes isolated from various soils. The Digestion Aid Enzyme package used by ECS, claims possible benefits as a feed additive. This feed additive is non-pathogenic, thus appears to be of no threat to our agroecosystem. Some testing, using some of the enzymes included in this formulation, has demonstrated that they do in fact stimulate many of the microorganisms

listed in the Anderson text. To address the salt index and its solubility more specifically, Digestion Aid Enzymes measure on the salt index at the "none detected" level. The anti-caking carriers: Included in this response, is the mining information for each of the carrier materials, along with an analysis of each. The silica salt index shows "none detected;" the kaolin clay sodium, "none detected;" and the peat indicated sodium at 96 ppm. When all ingredients are mixed together in the feed additive at the rate of two and one half pounds (per ton), you will have a total of 19 ppm sodium, which equates to .000019 percent. Now add this 19 ppm sodium to 2000 pounds of feed and the cows and pigs will picket for a salt shaker. Obviously, neither the crops nor the soil will experience damage.

QUESTION 6: *The alternatives to using the substance in terms of practices or other available materials.*

RESPONSE: To address the alternatives of using the "substance," Digestion Aid Enzymes, is a difficult task. It is difficult to list alternatives with efficacy comparable to the Digestion Aid Enzymes, because we know of no other such product that has been approved by OMRI. The issue is: People and animals spend more energy digesting food in one day than any other one task. This problem is compounded when, for example the animal is pushed to the limit for earlier development or greater productivity. When under stress, the native source of enzymes may slow down, causing a lack of ability to keep up with the demand. In addition, the animal may find the type of feed to be incompatible with their natural production ability to provide adequate Digestion Aid Enzymes. In any case, where there is a shortage of Digestion Aid Enzymes by the animal's own natural provision, multiple health problems may occur and degenerate mutations may be set into action (reaction). Consider a second example: Humans are not exempt from this type of problem and we may be able to relate more quickly with the illustration. Insufficient Digestion Aid Enzymes in a human can result in indigestion, poor nutrient balance, excess weight, nervous stomach, acid imbalance, heartburn, constipation, diverticular disease, inflammatory bowel, gas, peptic ulcers, diarrhea, leaky gut syndrome, etc. Animals are somewhat similar.

QUESTION 7: *Its compatibility with a system of sustainable agriculture.*

RESPONSE: Digestion Aid Enzymes are beneficial for animals. These enzymes are compatible with a sustainable agriculture system, since they help round out the cycle of probiotic philosophy, microbial balance and the enzyme army. Many ideas come and go. Many fortunes are acquired when an innovative person or group is strong enough to sell a program. For example, the NPK, herbicide and pesticide programs have lasted for 40 to 50 years. Lots of money has been made off of the agriculture business. However, as ideas come and go and the promoters sell their way to comfort and fortune, the particular experiments may begin to show signs of multiple problems. When nature is violated, it is only a matter of time until we correct it or until things become bleak enough to necessitate nature regenerating itself. For thousands and thousands of years, people have lived off of the land. Nature has a built-in remediation plan. It always has, and probably always could. When nature's laws are broken, the ones breaking them may find themselves broke and broken. I believe in balance, microbial cleansing, and enzyme management. After each painful experience, agriculture will

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survive. After hazardous waste and chemical mistakes, our land will endure. There are cycles in nature which endure. For example, bio-dissipation of odor can be seen as waste turned to compost; bio-transformation is seen as worn out soil is replenished; bio-restoration of waste waters and polluted soils; and bio-remediation of environmentally hazardous materials. Microorganisms and enzymes make up nature's redeeming army!

Digestion Aid Enzymes are such a small part of this balanced plan. But they work. Are they compatible with a system of sustainable agriculture? YES, ALWAYS. Nothing fancy, just functional.

Sincerely,

William R. Jackson, Ph.D.
Consultant

encl.
